UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CIVIL ACTION NO. 13-1039(FLW-TJB)
CIVIL ACTION NO. 13-13

IN RE PLAVIX PRODUCT LIABILITY AND MARKETING LITIGATION, etc., et al., Plaintiffs v. BRISTOL-MYERS SQUIBB COMPANY, et al., Defendants	:	TRANSCRIPT OF MOTIONS
	:	AUGUST 21, 2013
STATE OF WEST VIRGINIA, et al, Plaintiffs V. BRISTOL-MYERS SQUIBB COMPANY, et al.,	:	

CLARKSON S. FISHER UNITED STATES COURTHOUSE
402 EAST STATE STREET, TRENTON, NJ 08608

B E F O R E : THE HONORABLE FREDA L. WOLFSON, USDJ

A P P E A R A N C E S :

ROBERT L. SALIM, ESQUIRE (LA)
-and-
FRANKOVITCH ANETAKIS COLANTONIO & SIMON, ESQUIRES
BY: CARL N. FRANKOVITCH, ESQUIRE (WV)
-and-
BRACEWELL & GIULIANI, ESQUIRES
BY: HEATH NOVOSAD, ESQUIRE (TX)
-and-
ATTORNEY GENERAL OF WEST VIRGINIA
BY: DANIEL GREEAR, DAG (WV)
On behalf of the Plaintiffs

(Continued)

* * * * *

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A P P E A R A N C E S (continued):

ARNOLD & PORTER, ESQUIRES
BY: ANAND AGNESHWAR, ESQUIRE (NY)
DREW HARKER, ESQUIRE (DC)
DAVID D. FAUVRE, ESQUIRE (DC)
-and-
LOWENSTEIN SANDLER, ESQUIRES
BY: REBECCA VISVADER, ESQUIRE
On behalf of the Defendants

A L S O P R E S E N T:

PARKER WAICHMAN, ESQUIRES
BY: DANIEL C. BURKE, ESQUIRE (NY)

C E R T I F I C A T E

PURSUANT TO SECTION 753, TITLE 28, USC, THE FOLLOWING TRANSCRIPT IS CERTIFIED TO BE AN ACCURATE TRANSCRIPTION OF MY STENOGRAPHIC NOTES IN THE ABOVE-ENTITLED MATTER.

S/Vincent Russoniello
VINCENT RUSSONIELLO, CCR
OFFICIAL U.S. COURT REPORTER

(In open court.)

THE CLERK: All rise.

THE COURT: Thank you.

I'll have the appearances. Everyone else may be seated.

MR. SALIM: Robert L. Salim for the plaintiffs, your Honor.

Mr. Carl Frankovitch for the plaintiffs West Virginia.

MR. NOVOSAD: Keith Novosad for the qui tam plaintiffs.

MR. GREEAR: Daniel Greear from the West Virginia State Attorney General's Office, the state of West Virginia.

THE COURT: Thank you.

MR. AGNESHWAR: Anand Agneshwar, Arnold & Porter, for the defendants, your Honor.

MR. HARKER: Drew Harker, Arnold & Porter, for the defendants, your Honor.

MR. FAUVRE: Your Honor, David Fauvre, on behalf of the defendants, with Arnold & Porter.

MS. VISVADER: Rebecca Visvader from Lowenstein Sandler, also on behalf of the defendants.

THE COURT: Thank you.

I'm going to first address the motions

regarding the Relator's case which includes the motion for suggestion of remand and the motion for reconsideration by the defendants of the transferor court's opinion, and then, after that, I will turn to the West Virginia motion.

Let me begin then as follows:

First, I think we need to kind of set some background rules as follows, which are that with regard to all of the issues that we'll be addressing today:

Would the parties not agree that under the MDL rules that if it is a procedural issue, it is addressed by the law of this Circuit, the transferee court; if it is a diversity case, I would be addressing the substantiative law of the transferor court; and, for a federal question issue, I'll be using Third Circuit law?

Do you agree with that?

MR. AGNESHWAR: Yes, your Honor.

MR. NOVOSAD: Yes, your Honor.

THE COURT: Then we have some parameters to go with. Thank you.

So let me begin with, first of all, the motion for suggestion of remand, and that is the motion that has been filed by the Relator in this matter. I

really do not need argument on this point. I think in this regard the only argument really is that the Relator indicates that essentially this being a false claims case, qui tam, that it's unique and procedurally complex. That makes it somewhat different than my products liability MDL cases.

Nobody disputes the theories of law; the elements of cause of action are different. Correct? The only issue is -- and as the MLD panel looked at -- whether there is an overlap, at least, of a factual issue in these cases. Right? That's what they found. You can't deny that there is; can you?

Who is arguing this point?

Give me your name one more time, please.

MR. NOVOSAD: Heath Novosad, your Honor.

THE COURT: All right. I have you, Mr. Novosad. Go ahead.

MR. NOVOSAD: I do believe there is a factual difference.

THE COURT: Not if there are factual differences. I asked the question: Is there an overlap of at least some factual issues? Can you deny that?

MR. NOVOSAD: Potentially, but the focus of the qui tam and the marketing cases is on the efficacy

of Plavix as compared to aspirin, and the focus of the PI -- the personal injury cases is whether there was sufficient warnings about the bleeding risks of Plavix such that there weren't sufficient warnings of the bleeding risks. And, so, the fundamental nature of the two types of cases are different.

THE COURT: You would disagree with that.

Who is arguing this one?

MR. FAUVRE: Your Honor, David Fauvre.

We would disagree with Relator's point on that. And if you look at our opposition, we do note citations from their complaint where they allege, as do the product cases, that defendants understated Plavix's bleeding risks relative to aspirin. The products cases do make allegations that defendants promoted Plavix as superior to aspirin, which is the central allegation in the qui tam case.

There are also similar allegations regarding the FDA letters at issue in the case and about the companies' representations about the clinical studies. So those are all overlapping factual issues that the panel considered in making its determination.

THE COURT: I've reviewed the complaint and, frankly, I find the same to be true. There clearly is an overlap in the kinds of factual allegations, and it

did reference the studies with regard to bleeding risk. It does talk about efficacy with regard to aspirin versus Plavix; and, frankly, I think that's what's going to come out probably as well in the product cases as well. There is going to be that discussion of efficacy. And certainly the marketing practices are front and center in the products liability cases. There I know we've dealt with already in some of the motions as to the learned intermediary doctrine, but it's talking about how it's being marketed and to whom, what the representations were. There is an overlap of factual issues and there is no doubt about that.

As a result, and which is all that needs to be done, the MLD panel so found, and that they found that there were numerous allegations with regard to marketing in both kinds of cases, and that it was appropriate therefore to consolidate. This Court would agree. All the cases I think are ultimately going to also come down to an inquiry with regard to efficacy of Plavix as well, all of them.

These commonalities are certainly sufficient to find that centralization is appropriate. I will not disturb the removal to this Court. I deny the motion for suggestion of remand.

Let's turn to the more substantive aspects now of the case. Who is going to be dealing with the reconsideration motion?

MR. NOVOSAD: I will again, your Honor.

MR. HARKER: Your Honor, I will deal with that one for the defendants.

THE COURT: You are?

MR. HARKER: Drew Harker.

THE COURT: All right.

With regard to the reconsideration, as well there is no dispute that this Court has the right under certain constraints obviously to review that ruling. Correct?

You are not disputing that. Correct?

MR. NOVOSAD: No, your Honor, we are not saying you don't have any jurisdiction.

THE COURT: Thank you.

And essentially everyone as I think also thought to look at this as does it fall within the, what we would call our 7.1(i) rule, our reconsideration contours. Correct?

MR. HARKER: Yes, your Honor.

THE COURT: So let me start with that. The first question I think I want to ask is: Looking at the opinion from the judge, and I think that the

Relator has conceded this as well, that nowhere did the judge specifically review or invoke Medicaid; did he?

MR. NOVOSAD: He does not mention Medicaid, your Honor, no.

THE COURT: Is that not alone a basis for this Court to find that he overlooked the argument -- well, let me start with this, by the way. The brief you filed below didn't highlight it either. I looked back at your brief.

MR. HARKER: That's correct, your Honor.

THE COURT: It didn't highlight Medicare D and it didn't highlight Medicaid. It spoke in general terms.

MR. HARKER: We were dealing with the complaint which also spoke in very general terms, your Honor.

THE COURT: I understand. But you didn't highlight it for the judge, and I know there was no reply, and I've seen the argument. Bottom line -- there wasn't a reply, et cetera, but it didn't highlight it. And the bottom line is when the opposition came, you made your arguments with regard to the reasonable and necessity requirement and why you followed that, and you did it under Medicare, et

cetera, generally, but the judge never mentions Medicaid even though that's part of your complaint.

MR. NOVOSAD: He doesn't mention Medicaid. But it was in the complaint and it was an issue for him to consider.

THE COURT: Isn't it there to think by reading this that it's at least unclear what he did or that he overlooked Medicaid, because he clearly used the term "Medicare" as a general word, and throughout the opinion he refers to "Medicare" generally and never invokes Medicaid.

MR. NOVOSAD: Never invokes Medicaid, that's correct.

THE COURT: I think that's a basis at least with regard to the Medicaid arguments for me to consider the Medicaid arguments. I do not believe they were ever considered in the first instance; and, as a result, it would be I think an error to not reconsider that for which there is no opinion in my mind. So I will hear arguments with regard to Medicaid today and whether the complaint is properly pled.

Now, with regard to Medicare, and specifically the focus of Medicare Part D. This is a prescription drug. Medicare D is what controls it. Correct?

MR. NOVOSAD: Yes, your Honor.

THE COURT: Really, Sections Medicare A, B, et cetera, don't deal with prescription drugs. Right?

So while the judge spoke generally about Medicare and didn't focus on Medicaid D, also within his opinion essentially the cases he cites deal with Medicare A and B; don't they? They don't deal with prescription drugs and how Medicare is applied.

MR. NOVOSAD: I believe the cases he cites to specifically are Medicare's A and B. There is plenty of law out there that Medicare Part D also has reasonable and necessary standards.

THE COURT: I know that's the argument and that's what we are going to talk about today. But what I'm suggesting is, the first question I have is, I think that there needs to be at least clarification of the judge's opinion because it's not clear if he was focusing on the language of Medicare D, which I know has some exclusionary language.

And I know what your argument is going to be, why you think, nonetheless, reasonable and necessary gets read into it. But certainly the language of Medicare D is different than A and B; and since his general language was about Medicare, and he cites cases as to Medicare A and B, I believe that

reconsideration is appropriate at the very least for clarification purposes. It doesn't mean the result may be different but it's necessary.

So I am going to reconsider both aspects of the opinion: Medicaid in my mind in the first instance because it was never decided, and then the Medicare D.

So let's move from there now and talk about the substance of these motions.

Let's start with the Medicaid arguments because, in my mind, to some extent, they are going to be argued for the first time here today.

With regard to Medicaid, essentially the position of the defendants is that once it's essentially an on-label use and it's an FDA-approved drug, that's the end of the inquiry. You don't have another layer.

Is that correct?

MR. HARKER: The only other layer you would have, your Honor, is whether one of the four exclusions that are mandated in Medicaid have been applied by the states, and our argument on that is clearly that they haven't been.

But, yes, fundamentally, if it's on-label for an FDA-approved drug, the cases say that the states

have to, must reimburse for the prescription.

THE COURT: Now, with regard to Medicaid, what is your argument with regard to the reasonable and necessary -- and some of this may apply to Medicare D as well -- when the state is not taking any specific action with regard to excluding this from a formulary or any of that?

MR. NOVOSAD: Your Honor is very correct. The argument is going to apply I think to both Medicare and Medicaid. The defendants' position, as you've stated, is once the drug is approved by the FDA, every prescription for that drug for the indication the FDA-approved it for is automatically reasonable and necessary or medically necessary, and the plaintiffs' position is that for both Medicare and Medicaid that's simply not the case.

There is also a very important step, and that's the physician, the treating physician, prescribing physician, their decision whether the prescription is reasonable and necessary for Medicare, whether it's medically necessary for Medicaid, and that is a second safeguard that goes to the reasonableness and necessity.

THE COURT: Let me stop you for a second. Perhaps I'll turn to the defendant for just one

moment.

Is it essentially your position, because when a drug is approved, at least since the 1962 amendments by the FDA, it has to be approved for both safety and effectiveness?

MR. HARKER: That's correct, your Honor.

THE COURT: So you say a finding has already been made essentially.

MR. HARKER: A federal finding has been made as to that issue. That's correct.

THE COURT: So furthermore you don't need an additional layer of reasonable and necessary then.

MR. HARKER: That's correct. And I think that the federal cases that we cited, including Edmonds from Florida, essentially say the same thing. Yes, your Honor.

THE COURT: I'll turn to the plaintiffs at this point as well.

Using the term, "reasonableness," do you think that has some different meaning than safety and effectiveness? Because, clearly, at this point a large part of the argument is cost. Certainly, they are going to say whether Plavix is as effective or less effective than aspirin.

What they are really saying is nonetheless the

way you've touted this is it's so highly superior to aspirin, and we're going to charge 100 times more than we charge for aspirin, and if people understood that it wasn't so superior or superior at all perhaps no one would be paying this premium and government payors would certainly not be allowing this.

So I don't know if the argument is that on the reasonableness that's a different overlay when we get to cost as opposed to effectiveness and safety.

MR. NOVOSAD: It's an issue. The reasonableness of prescribing Plavix when the defendants knew that it was no better than aspirin for two of the three indications or may be worse than aspirin.

We know that the FDA on at least two occasions told them to stop marketing it that way. So there is not an issue, I don't believe it's going to be an issue, that they were improperly marketing Plavix, Plavix's efficacy, as compared to aspirin.

And so what they have basically done by these fraudulent marketing practices is to deprive the treating physicians of the ability to make their best judgment about whether a prescription for Plavix was reasonable or necessary.

This goes for many drugs for many of the

indications. Epilepsy, for example; there is a dozen anti-epileptics out there. Some may be approved for epilepsy, some may be reasonable for some types and some may not be reasonable for other types. It may be reasonable to try something else first as opposed to going to one or the other.

The same thing for Plavix. A patient who had a stroke before Plavix was on the market, if the doctor wanted to prescribe an anti-coagulant to help prevent another stroke or a heart attack or vascular death, would most likely prescribe the baby aspirin that costs four cents.

Plavix comes on the market. The defendants know that for stroke patients and for heart attack patients, myocardial infarction patients, Plavix is no better than aspirin. But their sales reps are trained to sell it as being superior. They leave behind pamphlets saying it's superior to aspirin. And so a doctor in many instance may think Plavix is this great drug, and so they issue these prescriptions instead of using the four-cent aspirin.

THE COURT: Have a seat for a moment.

So the argument is that it really is not the same inquiry or requirements as the FDA finding that it's safe and effective, which your position would be,

and that's the end of it now.

So if you prescribe an on-label drug which has already been determined as safe and effective, there is no reason to have an additional criteria of reasonable and necessary, though the statutes are written in such a way that that is possible perhaps.

But the argument being made is, the reason for having such an additional requirement -- I'm only discussing now why there could be an additional requirement as opposed to whether there actually is or not -- is that it can mean something different than what the FDA finding or determination was with regard to safe and effective because something can be safe, something can be effective in that it will treat the problem for which it's being prescribed, but it doesn't mean in a particular case perhaps that it is the necessary drug or that it is the reasonable drug to prescribe whether for cost reasons or otherwise.

I think there is probably some merit to the argument that was just made that they could have some different meanings. You wouldn't dispute it could have different meanings, reasonable and necessary, than safe and effective; would you?

MR. HARKER: I wouldn't dispute that, your Honor. They could have different meanings.

THE COURT: So we start with that.

Now, we'll start talking about the statutes themselves.

Have a seat for a moment.

So that I can also decide what this is as a claim, let me go through a couple of things.

The parties would agree that a False Claims Act cause of action imposes liability on a person or entity that both submits a false claim or causes a false claim to be submitted.

Now, your argument is essentially that the physicians are submitting the claim, they don't know it to be false, but that essentially they are being caused to submit it by the actions of the defendant. Correct?

MR. NOVOSAD: That's correct.

THE COURT: And it's causing them to submit this to the government. That's your only argument, is the causing.

Correct?

MR. NOVOSAD: That's correct, your Honor.

THE COURT: All right.

I think you would also agree, and certainly the case law seems to indicate, there are two types of false claims: those which are factually false and the

claims which are legally false.

Isn't it true that your theory of liability, the Relator's theory of liability that was advanced before the transferor court and this Court, is that this is a legally false claim?

MR. NOVOSAD: Yes, your Honor.

THE COURT: Thank you.

And would the parties agree that to demonstrate legally false claims in this case, that the Relator would have to show that the defendants caused the submission of the claims that did not comply with the applicable statutes or regulations, and that compliance with which was a precondition to payment by Medicare Part D and the individual state Medicaid programs?

Would you all agree with that statement?

MR. NOVOSAD: Yes, your Honor.

MR. HARKER: Yes, that's what Judge Greenberg said in Wilkins, your Honor.

THE COURT: It sure is.

So now we're in agreement on that, because there was some disagreement in the briefs about legal, factual, et cetera. We have now set the parameters of what the cause of action has to be.

Let's first turn then to Medicaid.

First of all, I know that the complaints do not actually plead a reasonable and necessary requirement.

Do you think that has to be pled?

MR. HARKER: Yes, your Honor, I do, both under Organon and Takeda. Yes, those cases are False Claims Act cases, and they make it clear that complaints are deficient unless they specifically set out the program that did set forth the condition for payment and the way in which the claim was false versus that as condition.

So, yes, your Honor, the complaint is deficient in that regard.

THE COURT: The "program" meaning Medicare or Medicaid?

MR. HARKER: That's correct.

THE COURT: What do you say about that?

MR. NOVOSAD: Paragraph 71 of our complaint, which is specifically our first cause of action for the federal false claim, does say:

"BMS/Sanofi's actions knowingly caused physicians and pharmacists to either expressly or impliedly make false certifications about Plavix's efficacy or necessity for the patient's treatment. As a result, BMS/Sanofi knowingly caused a submission of

false claims by government payors."

I do not believe the remaining causes of action mention medical necessity, but the pleadings are there. The claims, the reasonableness and necessity are part of the complaint.

THE COURT: All right.

That doesn't say "reasonableness." We've already discussed that efficacy is something different than reasonable. But I assume your argument would be: Well, even if I didn't plead it properly, I could amend.

MR. NOVOSAD: If the Court is of that mind, we would ask leave to amend. We think the complaint is sufficient on its face. But for that matter we would ask leave to amend.

THE COURT: I think you would have to use the buzz words, and they are not just buzz words because as we've already indicated talking about efficacy I think goes right as to perhaps just the statute. The reasonable and necessary requirements are a little bit different, and I think you would have to, and you would have to be able to do so in good faith. That's a pleading issue and certainly amendments could be appropriate.

But let's talk about your position, which I

think you are saying that is not a part -- we are going to start with Medicaid -- of the Medicaid program.

MR. HARKER: That's correct.

Well, certainly with respect to the terminology in the complaint, efficacy or necessity, you don't find that in the Medicaid statute.

THE COURT: Put that apart. We're at the beginning. Amendments are fine.

So assuming they would amend to include that language, now let's talk about it.

MR. HARKER: Okay.

Our view, again, would be that with respect to the allegations in the complaint, which are all for on-label use, stroke, or what have you, no off-label being indicated, the condition for payment here set out in the Medicaid statute made very clear by Congress, a mandate -- and many, many cases say the same thing, that the states have to reimburse for an on-label accepted, medically accepted indication, in the absence of one of the exceptions. I understand that they could amend their complaint. But, as of now, there is no allegation as to any of the exceptions.

So what you have are allegations related to

on-label uses for a medically-approved drug without any of the exclusions, Medicaid Congress mandates reimbursement.

So going back to Judge Greenberg's opinion in Wilkins, they have not alleged and cannot allege, in my view, a condition for payment based on what their basic factual allegation is, which is all on-label uses.

THE COURT: What would you say in response?

MR. NOVOSAD: We don't disagree that we are alleging on-label uses. We are not making any allegations about off-label in the qui tam. I think it still comes back to -- I don't believe there is any case law that the defendants have cited that say automatically every on-label prescription for a drug is medically necessary or is reasonable and necessary.

Whether or not Medicaid and Medicare must reimburse for on-label -- let's assume for the fact that is true. I don't think that's necessarily the case. But assuming that Medicare and Medicaid have no choice but to reimburse for on-label prescriptions, you still have the requirement that prescription must be, for Medicaid, specifically, medically necessary. That's a determination that's made by a treating physician when they see their patient, whether it is

necessary for that patient to be prescribed Plavix or whether something else would be more appropriate.

THE COURT: So the argument basically is because the doctor has to still certify for Medicaid purposes that something is medically necessary.

Would you agree with that?

MR. HARKER: No, your Honor, I wouldn't.

THE COURT: You wouldn't.

MR. HARKER: No. It hasn't been pled and --

THE COURT: Forget the "having been pled."

MR. HARKER: No, I wouldn't agree with that.

THE COURT: Why?

MR. HARKER: Because with respect to this particular -- these particular usages, they are on-label. They are on-label. They are for an FDA-approved drug. You look at the statute which clearly says that they must be reimbursed if that's the basis without more.

Look at Edmonds, your Honor. I would encourage you to read Edmonds closely. We have. Edmonds was interesting because the state tried to impose some extra requirements onto what medically accepted indications were and exclude, exclude from the reimbursement in Florida indications that the statute mandated should be reimbursed.

And in Edmonds the Court found that those extra conditions, if you will -- which is exactly what we are talking about here with this concept of this medical necessary overlay, if you will, on top of the federal requirement -- that the medical necessary overlay they are talking about is exactly the kind of thing that the Edmonds court said Medicaid doesn't permit unless the states follow one of the four, what the Court called, carefully circumscribed exceptions that are set out in the statute. Unless the state follows that, then the on-label indicated use must be reimbursed, and without respect to any additional requirements.

So what we are saying is that the states -- within the confines of those four exceptions that are set out in the statute, the states could impose additional requirements. But there's got to be within the context of those four exceptions, those four exclusions from the basic guarantee of reimbursement, and that hasn't been done and certainly hasn't been pled.

MR. NOVOSAD: Again, your Honor, I think we are talking cross-wise. For the purpose of today, let's assume everything they said is right, that the state does not have the ability, no discretion,

whether or not they have to reimburse for an on-label usage.

What we have in the complaint are Relator, former sales rep for the defendants, said that they were instructed to target physicians in low-income areas because those doctors have a higher percentage of patients on government assistance like Medicare and Medicaid; and, ironically enough, low income patients are less price sensitive than higher income.

THE COURT: I know your argument. His argument is: But the state could not restrict that unless it falls within the four criteria, and you haven't pled nor suggested that you would plead that it could fall within the four exclusions.

MR. NOVOSAD: Because there are bases upon which the state can refuse to pay; then there is the medical necessity requirement that is certified by the doctor.

If the government has no choice, that's what the False Claims Act is for. They promoted Plavix in a way to vastly increase the amount of prescriptions for people who it's not medically necessary for; and if the government has no choice but to pay those, that is causing a false claim to be submitted that the government has to pay, and that's the purpose of this.

It comes back to their bad actions that the FDA at least twice told them to stop doing.

THE COURT: I asked the question: Does a doctor who submits a claim for the patient, the patient submits a claim for reimbursement, is there a medical necessity certification that is essentially being attached by making that claim?

MR. HARKER: Not in the case of Plavix on-label indications; no, your Honor.

THE COURT: Isn't it inherent that it has to be; that anytime that a physician is prescribing, they are determining or they have determined that there is a medical necessity for that prescription?

MR. HARKER: That's not contemplated within the Medicaid statute. You say is it inherent, as I say --

THE COURT: Isn't that part of the scheme for Medicaid? The whole idea for this kind of government program was that you are going to make claims for things that are medically necessary for patients. You are going to get government money repaying. You wouldn't do something that's not.

Look, you could have a drug that's FDA-approved and on-label and a doctor says, Well, maybe you could develop a little bit of high

cholesterol here. I'm going to give you Crestor or Lipitor for it. You're not really there. Maybe it's not really medically necessary.

To get it repaid, they have to be saying it's medically necessary to prescribe this drug. Right? Isn't that inherent?

MR. HARKER: They are making a judgment, your Honor.

THE COURT: Exactly. But you just conceded that then.

So their argument is that the judgment has been skewed by your marketing, and that they can make a claim in that regard which is causing them to submit claims.

MR. HARKER: Well, your Honor, I'm glad that you got back to the language of the False Claims Act because that's where we start; and if you look at Judge Greenberg's opinion, the certification -- assuming that there is a certification -- of reasonableness, it must relate to a condition of payment, and what we have searched for in the context of Medicaid is that condition of payment. That the state had a basis under the statutory scheme set out by Congress to deny the claim for payment, and because Congress set up Medicaid the way they did, there is

no -- the state, if they wanted to impose such a condition, they could do so, but it's got to be within the context of those four exclusions which I think it's just been conceded they couldn't plead to.

Wilkins also addressed the issue about: Are there other remedies here? The False Claims Act deals with false claims for payment, and the allegation in the Wilkins case was with respect to Medicare marketing regulations. The Court there said, We've heard a number of times about FDA. The authority of FDA has been invoked here.

Well, the FDA has authority to deal with the kinds of allegations that are being made here -- false marketing. And what Wilkins said was the Court shouldn't substitute as judgment for what has really been set up to be an administrative remedy here. Go to the FDA and let the FDA deal with claims about false marketing because the FDA is best suited to do that.

With respect to what Wilkins was looking at and what your Honor is looking at, I would submit to you that you need to look for a condition of payment, and the condition of payment needs to specifically say that the doctor has to certify as to its reasonable and necessary -- that this is a reasonable and

necessary prescription, and there is no requirement to do that. There is just no requirement to do that, nor has one been pled.

THE COURT: So under your theory, unless the plan sponsor, provider, et cetera, adopts a system that excludes unreasonable or unnecessary drugs, then any prescription must be paid for, including anything that's a more expensive drug than one that is equally effective or is cheaper or equivalent. That's your position. There's no choice. Cost never comes into it.

MR. HARKER: And, indeed, your Honor with respect to that question --

THE COURT: Is that right, cost never comes into it?

MR. HARKER: Yes. And I would say for support for that, I would encourage your Honor to look at the formulary provisions in the Medicaid statute because the formulary provisions -- this is one of the four exceptions that we are talking about.

THE COURT: I have the requirements for formularies. What do you want me to look at?

MR. HARKER: The one that says -- let's see. I'll tell you.

It's Section 1396r-8(d)(B)(iv). And you will

see there, your Honor, that there is a reference with respect to formularies that "a covered outpatient drug" -- this is Plavix now; Plavix is a covered outpatient drug about which there is no dispute -- "may be excluded with respect to the treatment of a specific disease or condition for an identified population, only if, based on the drug's labeling, or in the case of a drug the prescribed use which is not approved" -- the pertinent part -- "the excluded drug does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs included formulary," and there is a written explanation of the basis for the exclusion."

What that is saying is that if in setting up the formulary the state looks at two completing drugs, and you look at the label and one drug is more effective, has efficacy advantages over the other, you can exclude from the formulary that drug.

THE COURT: I have it. I read it with you and I have it in front of me. Thank you.

MR. HARKER: And without any reference to cost. I'll just make that point. No discussion with respect to the formulary about cost and cost

advantages and taking into account cost issues.

So in setting up a key exclusion from the federal mandate of guaranteed reimbursement for approved drugs, Congress itself did not focus on cost. I think that's a terribly important consideration for us to the extent that we are looking at this issue of the difference between Plavix and aspirin in terms of cost.

(Continued on next page.)

THE COURT: But there is more than that. It does talk about, put aside the cost, "and does not have a significant clinically meaningful therapeutic advantage." That would be the second part of their argument.

Put aside the cost. You can add that to it and think about it. But what they are saying is, and that is their claim, that Plavix does not have a significant clinically meaningful therapeutic advantage over aspirin, and therefore it is something that could be excluded by a formulary.

Now, I know your argument is that they haven't presented anything that any state actually excluded it. But my assumption is, the next argument would be: Well, one of the reasons they haven't is because you have so skewed your marketing and test results that not only are the physicians that you are targeting not aware, but the states who are creating and those who serve on these committees that create the formulary are not fully aware either.

By the way, you haven't pled that because that was my next question. You've only pled as to physicians being essentially marketed and hoodwinked. You haven't said anything about this being aimed at those at the state level or -- we'll get to Medicare

Part D -- the plan sponsors and providers. It's not pled.

Wouldn't that have to be for you to be able to make a claim under these statutes?

MR. NOVOSAD: I don't think that necessarily does have to be pled to make a claim under these statutes.

Your Honor hit the nail on the head. Our allegation, your Honor, is that there is no significant clinical advantage of Plavix over aspirin for two of the indications. But I still think you do have the cost issue as well.

Montana, for example, specifically in its Medicaid regulations said that "prescription drugs must be medically necessary and the most efficient and cost effective."

So they are requiring this, and physicians, because they have been told that Plavix is so much better than aspirin, don't get to that cost assessment. If they were told the truth, that Plavix is no better than aspirin, maybe worse than aspirin for these groups of people that suffered stroke or --

THE COURT: Could I just stop you one second.

Would Section E of the section you were reading have any impact on cost? You were in

subparagraph (4), (e) says as well:

"The formulary meets such other requirements as the Secretary may impose in order to achieve program savings consistent with protecting the health of program beneficiaries."

Does that put an overlay of cost into the equation?

MR. HARKER: Yes, your Honor -- well, all of those provisions that we are talking about have to be met in setting up a formulary.

THE COURT: So couldn't cost be an issue in creating a formulary together with the others, is what I'm saying, a consideration of cost by looking at Subsection E?

MR. HARKER: Assuming that it's met.

THE COURT: So it's not that cost could never come into the equation of creating a formulary assuming the other criteria are met as well. That's all I wanted to point out. You indicated cost never comes into it, but apparently it does under the statute. So there can be the argument made, both cost and comparison with other drugs and whether there is a significant therapeutic advantage.

I go back to, however -- because I know you have not pled that any state has created a formulary

that excludes it. I've essentially made the argument for you, I guess, that what you would argue is that one of the reasons they haven't is because the information hasn't been adequately given to them as well with regard to this drug.

But it's not pled. And I raise that to you because while I understand your argument is that it is the physicians who are submitting the claims and being caused to submit what you would say to be false claims, must you not be pleading as well if, indeed, there is no exclusion from the formulary list by a state, would you not have to be in good faith able to plead that while there is not, the reason is, again, because of this false marketing, which means it's not adequately pled still.

MR. NOVOSAD: What we come back to, your Honor, is even if it's an on-formulary drug, the medical necessity requirement is an independent check on the Medicaid system that their fraudulent marketing caused physicians to submit these claims.

So even, again, if the state had to reimburse, if there was some rule that says if there weren't these exceptions that states could limit their formulary, let's say, any drug approved by the FDA you have to have on the formulary, it's still a bad action

by the defendants causing excessive prescriptions to be written and violating the medical necessity requirement which is an independent issue that's dealt with at a physician level.

So I think you can do it both ways. You can do it either way. One is to say the defendants hoodwinked the states into keeping Plavix on the formulary for strokes and MI patients thereby having the states reimburse these prescriptions. But even if that wasn't the case, I think you still get there with the independent medical necessary requirement that applies to the physicians and their decision whether to prescribe Plavix.

THE COURT: Well, except that the physician isn't looking at cost. It's not their concern except when it has to be their concern when a patient can't pay for it and they are looking for something else. They are not worried about cost in this situation.

Where you talk about efficacy, the argument would be, you haven't argued it's not as efficacious as aspirin. You are just saying it's not significantly better.

MR. NOVOSAD: It's not significantly better and it may be worse. The studies have -- it's unclear. That's why the FDA told them to stop.

THE COURT: I don't really have anything that would make that -- to be clear that you could plead that. But in that regard, when you talk about medical necessity for the doctors themselves without a consideration of cost or whether it's significantly better, I'm not so sure at that point you could argue that that becomes a false claim in saying that this is a medically necessary drug because they don't have to do at that point a comparison of saying: Is there something cheaper out there that would do the same thing?

MR. NOVOSAD: I think for some states, Montana specifically, you do have to do a --

THE COURT: I don't know about Montana. You haven't pled that. You haven't pled anything else as to the other states as to why, then, that overlay would come in where that could be a consideration. I don't think it's been properly pled under Medicaid. I'll give you a chance to plead it again.

So I'm going to at this point dismiss without prejudice the Medicaid allegations with the right to replead.

Let's turn to Medicare Part D. Where are we here? What's your argument? I've read it all, but I'll let you summarize it now in light of everything

we've said.

MR. HARKER: Well, it really is very consistent, and you're probably not surprised, your Honor, with our Medicaid argument in the sense that when you look at Medicare Part D, what did Congress say? What Congress said was that covered Part D drugs, which, again, are FDA-approved for an indicated use, must be reimbursed under Part D unless there is a -- unless one of the exceptions applies.

I know that there is an argument that has been made that, no, there is a reasonable and necessary standard that also applies to Medicare Part D, although Congress knew when they wanted to condition payment on a reasonable and necessary requirement, they knew how to do it.

So if you look at the Medicaid A and B statute, what does it say, your Honor? It says, "no payment may be made under Part A or B or Part B of this subchapter for any expenses incurred for items or services" -- I'll skip over a few words -- "that are not reasonable and necessary for the diagnosis or treatment."

So Congress spoke very clearly in A and B when they wanted to impose a reasonable and necessary requirement on payment. They knew how to do it. They

didn't use that same language with respect to Part D.

Instead, with respect to Part D, what they said was that Part D covered Part D drugs, as I've just defined them, have to be reimbursed and unless an exclusion is met or a circumstance is met. And one of the circumstances is that a Part D plan may proactively impose a reasonable and necessary requirement as part of its reimbursement policy.

That's not been pled, your Honor. So what we have is, we have the condition of payment here is that an FDA-approved indication must be reimbursed under Part D unless certain circumstances are met. Those circumstances not being pled, our view is the condition for payment is it's FDA-approved and it's for an indicated use. If there is any implied certification here, your Honor, by the doctor, that's what he's certifying to and that's it.

THE COURT: Counsel.

MR. NOVOSAD: What we have in 42 U.S.C., 1395w-102(e) is that Congress specifically authorizes prescription drug plans to exclude from qualified prescription drug coverage any covered Part D drug that is not reasonable and necessary. It's a very similar argument to the Medicaid.

THE COURT: I understand. So we go back to

the argument of there is no indication that any plan sponsor has incorporated that language. Isn't that what the statute says: To get the reasonable and necessary requirement written into it, the plan sponsor has to make it a part of theirs?

MR. NOVOSAD: Again, we think that's one avenue. We also think there is the independent duty of reasonableness and necessity on behalf of the prescribing physician.

THE COURT: Well, except in the statute itself the way it's been written, for whatever reason, Congress decided that in Section Y, that they created this exclusion under D. They say that unless the plan sponsor includes it -- I'm sorry. It's W. And for some reason they did that way with prescription drugs different than regular services under A and B; and whether it's because they saw the overlay of the FDA having taken action and they thought that was appropriate, but they left open for plan sponsors to create this additional requirement which was already discussed earlier in this argument could have some additional meaning.

Do you not have to plead that in some way, similar to the discussion I just had with you, either that some of them did exclude, which I'm guessing none

of them did, or the argument that I just made for you essentially a few moments ago, that your argument might be one of the reasons such an exclusion doesn't exist is because they are also not aware because of the manner in which it has been marketed?

MR. NOVOSAD: The same arguments would apply, yes, your Honor.

THE COURT: And I think you would have to replead it then again. So I'll allow you to replead both of those claims, and we'll see where it goes from there and if you could do it effectively.

So the motion has been reconsidered, and I'll give an opportunity for plaintiff to replead within 30 days.

Now, let's turn to West Virginia.

MR. SALIM: Your Honor, if I may, I would like to introduce to the Court the Attorney General from West Virginia who is in charge of this case who has come today. He was not here at our initial conference, and I wanted to introduce Mr. Greear to the Court, your Honor.

THE COURT: Thank you.

Who is going to be arguing the West Virginia?

MR. FRANKOVITCH: I will be, your Honor. Carl Frankovitch.

THE COURT: Thank you very much.

So we are dealing with this in your motion for remand, and let me begin.

First of all, we're going to be talking about the real party in interest in this case during this argument. In that regard, is that a procedural as opposed to substantive issue?

MR. FRANKOVITCH: Not necessarily, your Honor. I think the substantive issue is the Attorney General's authority to act on behalf of the citizens of the state and statutorily created authority to act on behalf of the state. And so I think it's substantive, not just procedural.

THE COURT: Is it a combination?

I understand that I may have to look at what West Virginia does and actually, the whole system of the PEIA, et cetera, and I'll be looking at all of that. But when I'm applying the legal principles to it.

MR. FRANKOVITCH: Well, I think in what I guess we are relating as the standing issue, it's the substantive law of the state which creates -- part of it is statutory which gives the Attorney General the authority to enforce certain provisions and to seek statutory penalties which is created solely by

statute, and I don't think is procedural.

THE COURT: By the way, this was not briefed. I know it was brought up in the sur-reply that was filed. I did not want sur-replies, but there was one filed.

MR. FRANKOVITCH: I don't think it is even predominantly procedural.

THE COURT: Are you going to be arguing the West Virginia one?

MR. AGNESHWAR: I am, your Honor. Anand Agneshwar for the defendants.

I think there is both aspects to this. In terms of the standard that your Honor will apply to determine what is a real party in interest, my understanding is you will apply Third Circuit law.

In terms of applying that standard in determining what PEIA is under West Virginia, you will then look to West Virginia substantive law.

THE COURT: That's basically how I saw it. You disagree with that?

MR. FRANKOVITCH: No, I don't disagree to that aspect. I don't think that PEIA is the critical issue either.

THE COURT: I understand. We'll get to that in a moment.

Let me try and get down to really the issues I see in this motion. I would hope, Mr. Agneshwar, that you are really not going to be arguing CAFA jurisdiction here. You are just wrong on that one.

MR. AGNESHWAR: I was not going to focus on that part of the argument, your Honor.

THE COURT: Good. Because we are just going to get rid of that argument that that was a basis for jurisdiction here.

So what we really have instead is the question of really who are the parties in this case and, indeed, is the state a party? And if they are a proper party and an actual party, it ultimately doesn't matter what PEIA is. If they are not, then it obviously does matter what PEIA is in this matter, if it's an arm of the state or not.

And, of course, the last question is, this question of federal jurisdiction as well, but let's deal with the parties first.

In this regard, talking about West Virginia, there is no question, correct, that the Attorney General may bring lawsuits on behalf of the state of West Virginia? You would agree with that. Correct?

MR. AGNESHWAR: As a general proposition, yes, your Honor.

THE COURT: Then what is being argued is that the plaintiff has a substantial pecuniary stake in the outcome of the litigation because it seeks civil penalties of up to $5,000 for each willful violation that occurred during a four-year period.

The issue of the injunction, apparently from what I understand factually, and I don't know that it's being argued to the contrary, is essentially on a going forward basis mooted because you have represented -- and I don't know that you disagree with these -- that the marketing efforts that were being attacked had ended. Is that correct?

MR. AGNESHWAR: That's correct, your Honor. Plavix is now generic.

THE COURT: So, Mr. Frankovitch, I think you would agree that a prospective injunctive relief is not therefore still part of this case.

MR. FRANKOVITCH: Well, it would be to preclude the reintroduction of its same marketing aspects.

THE COURT: They would probably stipulate to that -- right? -- at the outset that they are not going to do that. Correct?

MR. AGNESHWAR: That we are not going to promote it unlawfully, yes.

THE COURT: Well, gee, you could do that for all of your drugs. Wouldn't you say that? That's not what you mean, that general statement. He means more specifically the manner in which you have marketed Plavix in the past with regard to certain claims.

Is that correct?

MR. FRANKOVITCH: Yes, the underlying aspect of this case, what we have depicted as unfair trade practices and deceptive marketing.

MR. AGNESHWAR: No, your Honor, I would not stipulate that there was anything wrong about the way the companies promoted the product.

THE COURT: I understand you are not going to put labels on it or say it was improper. The question is -- and as I understand it now to know whether this is really a moot point or not -- is: If there is a dispute between the parties as to the manner in which Plavix is marketed, you are thinking, of course, that everything that has been done to date has been fine, that they are saying it has not been, and even if they are not engaged in those marketing activities at the moment, the position is if you might resurrect those marketing activities that they claim to be problematic, they have a right to go forward and make sure that you don't and get a decision as to whether

it was improper so you would be enjoined from doing so in the future.

So my question to you is: Unless there was some agreement, whatever those marketing things are that could be agreed to, he's got a life claim on injunctive relief. You see the Catch-22 you are in?

MR. AGNESHWAR: Yes. Unless I'm willing to say that the companies will never market the claim in the future, I guess that theoretically has a claim for injunctive relief. But I would think that in order to file a claim for an injunctive relief, he has to have evidence that something is going on now that he needs to enjoin. So there is no ripe claim for injunctive relief.

Now, theoretically, if six months from now the companies decide, You know what, we want to get back in promoting the drug against the generic, and they do some marketing that he thinks is wrong, maybe there will be a claim for injunctive relief that becomes ripe then, but not now.

MR. FRANKOVITCH: They still have marketing material out there and having corrected what we perceive as being the improper marketing.

THE COURT: Mr. Frankovitch, are you telling me that there is currently marketing material out

there that you feel falls within the allegations of your complaint?

MR. FRANKOVITCH: There could be because there was paper marketing, there was advertising, there was instructions to staff, and part of that injunctive relief would be to desist from that activity, assuming we prove our case.

THE COURT: Right, or to seek return of it.

MR. FRANKOVITCH: Right.

THE COURT: Or to make curative instructions.

MR. FRANKOVITCH: Exactly.

THE COURT: I don't think the injunctive relief claim is dead.

MR. AGNESHWAR: I think we are back to pleading a little bit. There is nothing pled about what's going on today. The only evidence, the only allegations in the complaint about marketing stem from a decade ago where the FDA's untitled letters were written.

So, again, I would think that if they really want to keep a claim for injunctive relief, they have to plead something going on now.

THE COURT: Where do you think you have allegations that deal with the marketing that would be current at the time you filed the complaint? Because

you filed this back in when?

MR. FRANKOVITCH: I think it was February of this year -- excuse me. December of 2012.

THE COURT: Well, they certainly pled it as a present. By the way, this is not a summary judgment motion here. But they have pled it as, "At all times material herein BMS/Sanofi engaged in illegal marketing practices in West Virginia to promote the use of Plavix by affirmatively representing Plavix was a superior drug to aspirin for certain indicated usages" -- is paragraph 21 -- "when in fact Plavix is no more effective than aspirin for certain indicated usages."

Paragraph 23 deals with targeting the false and deceptive marketing efforts of the state and PEIA.

There is nothing that indicates that this is a backwards look, but that it was ongoing. And I'll take the allegations as pled at the time that you removed the case, and that's when I look at it, at the time of removal.

MR. AGNESHWAR: I can understand that position, your Honor. I would just submit, since you are asking me the question that under Twombly and Iqbal, there would need to be a lot more specificity than just saying that there were promotions that

happened over a long period without any evidence or any allegations but there are specific things going on today.

THE COURT: By the way, the Third Circuit has cut back a little bit on Twombly and Iqbal this summer, if you have seen the more recent opinion. I think they thought that all of us got a little out of control in trying to make Twombly and Iqbal have more real teeth for all of us in evaluating pleading. So I wouldn't be as sanguine that it's not -- that's not where we are, and this is not a motion to dismiss on adequate pleading, et cetera.

You removed it based on the manner in which it was pled in arguing they were not a proper party, and one of your arguments, of course, is that they could not go forward on injunctive relief. Essentially, it was a moot point. And I'm saying, the manner in which it was pled does not make it appear to be a moot point.

MR. AGNESHWAR: Yes, I understand that, your Honor, and I don't need to debate the point. Our real argument about that is that the State AG aspect of this case is really the tail wagging the dog; and if you do a real party-in-interest analysis, it's really not the gravamen of this complaint.

It's really about what the insurance fund was paying out and about reimbursing the insurance fund. And our real point about the injunctive relief component is: Look, come on; these companies are not out there promoting the drug today. You saw an injunctive relief component out there. It's really not -- it's not a significant claim.

Might it have some legs under a pure pleading analysis? Yes, I'll concede that it might have some legs because the complaint was drafted in the present tense, but it is really not the thrust of the complaint.

THE COURT: Let's talk about the penalties. The civil penalties are penalties apparently that are going to be paid to the state. This isn't the return of monies to PEIA or the fund. These are simply penalties that I guess the argument would go into the general treasury and not earmarked for the PEIA.

Is that correct?

MR. FRANKOVITCH: That's correct, your Honor.

MR. AGNESHWAR: Your Honor, we have an argument, the civil monetary penalties aspect of the claim that is not tied to the insurance recovery is not viable under West Virginia law because of the White case.

THE COURT: I know that's your argument under White. Now, talk to me about White because -- first of all, White specifically is -- I know you talked about no private cause of action. This is not a private cause of action. So, instead, I know what you would like to argue is, though, the reasoning of that, when put together with the Bear Sterns case in the securities context in a regulated kind of industry context, you said it carries a lot of weight as to why that analysis should apply as well to the state being able to bring a cause of action with regard to this kind of prescription drug.

Now, the J&J case, the West Virginia J&J case which you cite for a different proposition to argue why it's a federal question argument by looking at their briefing, nonetheless, in the J&J case didn't the judge there discuss the fact that these really are complimentary causes of action that may be brought together in a different part of the case?

MR. AGNESHWAR: Yes, your Honor -- well, I think more accurately the J&J case assumes for the purposes of that case that the claim is a viable claim; and because of the timing of when the J&J opinion came out and when White came out, I think it was all briefed separately. And the issue about

whether the claims are viable at all just honestly didn't come up in the J&J case. So the Court never really addresses the argument about whether these types of claims are viable.

THE COURT: Let's see. Bear Sterns was decided -- Johnson & Johnson I guess was in 2010.

MR. AGNESHWAR: And Bear, Sterns, 2005.

THE COURT: So they are well aware of the Bear Sterns case when they decided this five years later.

MR. AGNESHWAR: Well, I think, typically, Appellate Courts don't reach out to decide issues that are not squarely raised before it. That's the only explanation I can think of for why the J&J case didn't address that. It just wasn't briefed.

May I expand a little bit on the argument?

THE COURT: Go ahead.

MR. AGNESHWAR: If you look at what was going on in the Bear Sterns case and in the White case, I think the Supreme Court of West Virginia is trying to take the West Virginia Consumer Protection Act and give it back to its roots, and they are asking the question of: What is this Consumer Protection Act statute really intended to protect?

And what they say in the Bear Sterns case is, this is meant to protect gaps in other regulatory

schemes. When you have a situation where consumers have day-to-day expenditures, day-to-day interactions where there is no other broad regulatory scheme, that's where the Act comes in to protect consumers. But when you have detailed federal regulatory schemes that are being enforced by federal agencies, there is no gap there that needs to be filled. The federal agencies are doing that. So I think what the Supreme Court was doing was by putting a stop on that and taking it back to its roots.

And when you look at the White case, in particular, what's interesting about the case -- your Honor was right, the actual holding of the case is about private causes of action. But they reached out and in answering the specific question that was raised that was certified to as to whether causation is an element of a private cause of action, they answered that question in the broadest possible way.

THE COURT: They used the learned intermediary doctrine there. I think we're a little bit different purposes in the private cause of action versus one brought by the state. Aren't there different purposes? The state is coming in essentially looking for a penalty that's for the purpose of deterring a certain kind of action. Whereas, when the individual

brings the claim, it's really to benefit themselves and to right a wrong that was done to them. With those different kinds of purposes, and when you are talking about the marketing messages that are seeking to be deterred by a state, and those different purposes, if a state could not bring such an action for the purpose of deterrence and sending a message to others, wouldn't essentially that allow, then, the actions to simply go forward and essentially escape penalty for them?

MR. AGNESHWAR: No, your Honor, because there is the FDA there, and the premise behind the White case was not just the learned intermediary. The learned intermediary was particularly relevant for the prospect if there was a buffer between the alleged fraud and the actual consumer, but there was also the notion that this is a very heavily regulated industry. So it's very questionable as to whether this is the type of alleged fraud that the Act was intended to protect against.

THE COURT: I'm not convinced as you are that in the area of pharmaceuticals that the same result would obtain, that that was intended to be excluded. It's certainly not specifically excluded from the West Virginia Act, and we are at this point looking at this

state's law. There is no dispute about that at the moment.

MR. AGNESHWAR: Correct, your Honor.

THE COURT: I have some real questions about your position here and applying Bear Sterns to it.

MR. AGNESHWAR: Can I give it one more shot?

THE COURT: Yes.

MR. AGNESHWAR: Your Honor, to me I don't think they are different purposes. The AG component of the Act and the consumer protection private cause of action component of the Act, they were both enacted together by the West Virginia legislature, and they were both twin parts of protecting consumers from fraud in the state. It is the Consumer Credit and Protection Act. So it is designed to protect consumers.

So now there are two ways in which consumers can be protected in the Act. On the one hand, consumers themselves can file a private cause of action; and, on the other hand, there might be situations where consumers don't do that, especially when you are talking about the day-to-day cash transactions that the Act is intended to protect against. You are not going to see a lot of private cause of actions there. So the state can come in and

use its enforcement powers to enforce that same fraud. But the reason the state is doing that is because consumers are being defrauded under the Act. So it is fulfilling that mission of the Act to protect consumers.

And so when you apply that to our situation, and when you look at what the West Virginia Supreme Court is saying is, Look, consumers don't need to be protected here, and they don't need to be able to file private causes of action because, No. 1, you've got learned intermediaries, you've got doctors that have a lot of information before them, not just how the drug was promoted to make these decisions; and, No. 2, you've got this 800-pound gorilla in Rockville, Maryland, the Food and Drug Administration, that is enacting very detailed regulations that controls the companies.

So consumers don't need to be protected from any fraud. So if consumers don't need to be protected from the fraud, how can it be that the state Attorney General can nevertheless file an enforcement action to vindicate this fraud that the very consumers don't need to be protected against?

I don't think it makes any sense. I don't think that you can read White with the rationale --

now, they could have come at it a different way. They could have said, There needs to be reliance; and if you don't have reliance, you can't make a claim. But that's not how they came at it. They came at it as a policy matter as to what was necessary to protect consumers, and that policy applies equally here to the AG's context, and I don't think the state has said anything in their brief as to why those policies don't apply here.

THE COURT: Mr. Frankovitch.

MR. FRANKOVITCH: Your Honor, I think that the statute is clear in providing -- both the Insurance Fraud Protection Act, which is another statute that has been cited, and the Consumer Protection Act -- they clearly -- and there has been a host of cases that have emanated from the Attorney General's office that have gone through -- there is a recent case that I want to bring to the Court's attention.

THE COURT: What is that?

MR. FRANKOVITCH: It is the Pfizer case, the Attorney General v. Pfizer, that was decided after these briefs were filed. It was a remand case.

THE COURT: What's the cite on that?

MR. FRANKOVITCH: It is a Westlaw cite. It is 213 Westlaw 3927833.

THE COURT: Came out of which court?

MR. FRANKOVITCH: It's out of the Southern District of West Virginia remanding cases. It's a drug case, but it revolves around the application of patent law, and it addresses the preemption type of argument, but it also reaffirms the Consumer Protection Act viability of the state's claim.

THE COURT: In what context?

MR. FRANKOVITCH: In the context of issuing the remand based on the fact that even though there is a large body of federal implication in patent applications and antitrust -- it also involved antitrust.

THE COURT: It wasn't specifically then a pharmaceutical type case that we are talking about?

MR. FRANKOVITCH: It involved pharmaceutical patents.

THE COURT: Patents are different than dealing with the drug itself.

MR. FRANKOVITCH: Yes.

THE COURT: It didn't involve an FDA. Correct?

MR. FRANKOVITCH: That's correct.

THE COURT: We'll take a look at that case in any event.

MR. FRANKOVITCH: The Merrell Dow case from the United States Supreme Court clearly says the Food, Drug and Cosmetic Act doesn't create that cause of action. That's left for the states to enforce. So it is not where you have to rely on the FDA to give some enforcement or some relief. That's an element that can be utilized by the state.

THE COURT: Certainly, it's been argued a moment ago by counsel that with regard to even though recognizing White only dealt with the private cause of action, but the policy reasons for regulating this -- and I do note White was decided basically a month after the J&J case, so it did come later than the J&J case.

MR. AGNESHWAR: It did, your Honor.

MR. FRANKOVITCH: They're two different animals altogether. The White case is, you've alluded to, a learned intermediary that the fraud is perpetrated on as a result of language comes into play. That doesn't come into play on the Attorney General's. It is giving him enforcement powers in the unfair and deceptive trade practices, and it is not contingent upon the elements set forth in White, and they could easily have done that.

THE COURT: There is a fair amount of

analysis, though, in the White opinion looking at, indeed, New Jersey law as well, talking about prescription drug cases and consumer acts and highly regulated industries. And so I'll turn to you and say: Why isn't at least some of that analysis applicable here?

MR. FRANKOVITCH: Well, I don't think it's applicable at all. I think all we have to show in the remand context is that we have the possibility of going forward and establishing a claim. I don't think the Court is necessarily called upon at this juncture to determine essentially a summary judgment motion.

THE COURT: No, it's not, and I do want to put it in the right context. I do understand. Their argument was there is really a cause of action trying to determine whether you are a proper party. So I have to be looking at that. That's the overlay here.

Let's move on. I have your arguments in that regard.

So essentially with regard to -- I can just sum up -- with regard to the civil penalties aspect, essentially the argument, Mr. Agneshwar, is if they actually had a cause of action, civil penalties, at least they are a real party. But your position is you don't think they can bring their cause of action.

MR. AGNESHWAR: Yes, that's essentially it. But I would go one step further than that. There is another argument.

Even if the Court is not willing to conclude that White closes off the state AG component of it, at the most it's hanging by a thread. It's the next thing. And so I think that factors into the real party-in-interest analysis. I think under the Fourth Circuit case that the state cites, the court looks at the totality of the complaint and tries to figure out and has to figure out who is the real party in interest here.

And when you have a situation where they've interposed the state AG action, but the West Virginia Supreme Court has said those consumers don't need to be protected in this context, therefore, How can there be a division between consumers and the state?, and you have a complaint that is all really about the insurance part, the insurance companies that paid. That is really a peripheral aspect of the case.

THE COURT: Well, I don't know. Their civil penalty argument, if they think they can show every single time there was a willful violation, there could be a nice little pot for West Virginia on recovery. What is it, $5,000?

MR. FRANKOVITCH: $5,000.

THE COURT: $5,000 a violation.

MR. AGNESHWAR: My point is, at the end of the day, if a claim like that survives, then you are absolutely right.

But my point is that even if, notwithstanding the discussion in White that consumers don't need to be protected, even if the Court decides that there is enough because of the standards on removal to let it go, it's not going to survive. And I think ultimately whether it's a motion to dismiss or summary judgment or something else, because --

THE COURT: Well, at that point, if it didn't, wouldn't you at that point then move to remove once they were no longer a party in the case?

MR. AGNESHWAR: Well, there is the voluntary/involuntary rule that might factor in at that point.

My point is simply this: At the most, what it is, it's a peripheral aspect of the case that's a tack-on to four out of five counts that are really about PEIA.

THE COURT: Let's turn to PEIA then and let's take a look at what we've got there.

Now, let me look at some of the issues with regard to this entity.

Essentially, West Virginia is arguing that it really is just an arm of the state. I guess the director is appointed by the governor. Their funding comes from the state. But I have some issues here. I think you haven't been clear about this. If I look back at the statute, not only is the funding segregated, but the funding, as I understand it, is really coming from the state as the employer as for their employees.

Now, is there additional funding that the state provides that's separate from what they are giving for their own employees that are part of the pay of the PEIA system?

MR. FRANKOVITCH: My understanding of the way the system works is it's for public employees within the state which include state employees, but it also includes municipal employees, county employees, other state-related employees.

THE COURT: Exactly. So when you are arguing, though, it's an arm of the state, what I'm saying is, certainly, the manner in which you've briefed it, because you have taken a look at the funding issue, I note that while the state holds the funds, it says that "all monies received by the public employees insurance agency shall be deposited in a special fund

or funds as necessary in the state Treasury," et cetera, who is going to administer the funds. It goes on in that way. But it also indicates very clearly that, for instance, it appears that it's segregated funding for this agency for just their purposes. It is not coming out of general funds of the state.

MR. FRANKOVITCH: Well, it depends how you determine "general funds." The state gives them the money to put in the particular account.

THE COURT: But for the benefit of the employees. That's very different.

MR. FRANKOVITCH: For the benefit of the employees that are employed there, and controls the funds and dictates the operation of the funds, and it's -- I don't know how much closer you can get to being an arm of the state without being the state.

THE COURT: Actually, I'm looking at who makes the investment decisions.

MR. FRANKOVITCH: The investment decisions are through the Treasury, the State Treasurer.

THE COURT: All right. Have a seat for a moment.

Let me turn to you, Mr. Agneshwar. I'm sure you are going to tell me the fact that the director is

appointed by the governor, certainly it's not weighty, and serves at the pleasure of the governor.

MR. AGNESHWAR: Correct, your Honor. There is no question there is a state aspect to it. The governor appoints the director. The board members are appointed by the governor. But that is obviously not the issue or else there wouldn't be all this case law about whether an entity is really an alterego of the state.

The real issue is this with PEIA, and I think this is the fundamental inquiry under Third Circuit law: How are the funds set up? If it sues or if it gets sued, does it pay itself or does it come out of state funds? And PEIA is an autonomous entity for those purposes. The state actually only pays 25 percent of the money that PEIA gets. It's self-funded through premiums from both employers and employees; and what's interesting is it even goes beyond West Virginia.

THE COURT: Let me ask you this question:

When you said the state only pays 25 percent of the money, is the 25 percent it's paying as premiums for its own employees or is it other funding that's giving it?

MR. AGNESHWAR: It's only premiums.

THE COURT: That's what I was trying to ask your adversary as well. So whatever they are paying in, it's just for their employees' benefit, the same as the county, municipality, or other employers that are paying for their government employees.

MR. AGNESHWAR: Exactly, and it even covers non-residents of West Virginia who happen to work for the state of West Virginia. It can sue on its own behalf. Any money it recovers has to be used for the purposes of PEIA. It's just clearly a classic insurance entity that is set up for the benefit of state and county and other employees, but, other than that, acts autonomously.

So even when you look at the director, if you look at the statutory provision about how the director is supposed to operate, they are supposed to operate independently, and they are supposed to stay clear of politics, and all their decisions have to be as fiduciaries for the employees who are benefitting from the insurance.

THE COURT: I have issues with your arguments with regard to the funding of PEIA.

What other arguments do you have that PEIA is essentially an arm of the state? They are acting really as an insurance company.

MR. FRANKOVITCH: It is acting as an insurance vehicle to insure those people. I don't know that there is any additional arguments. But it is not critical to the Attorney General's viability in this case.

THE COURT: I hear you. There was the independent argument that if this Court were to find -- their argument is that PEIA is the real party in interest.

MR. FRANKOVITCH: Right.

THE COURT: So I know your argument is, Please look at the Attorney General, and that's enough to find that there is not diversity and send it back.

What I'm hearing at this point, you are really not going to be hinging your argument on PEIA.

MR. FRANKOVITCH: That's true.

THE COURT: Perfect. That's what I wanted to know.

The last argument is with regard to the question of federal question jurisdiction, and essentially the argument by the defendants that this is really involving federal questions. Right?

MR. AGNESHWAR: Correct, your Honor.

THE COURT: And in that regard, I know you've recently submitted to me the underlying brief that was

filed by the state in the J&J case where they essentially argued, Take a look at what the FDCA has done and you are controlled by that.

MR. AGNESHWAR: Yes, no more, no less.

THE COURT: What do you want to say about that? They've just submitted that recently.

MR. FRANKOVITCH: Yes, and I was familiar with it. I don't think that is relevant at all. There are many, many times in all kinds of litigation where you submit federal regulations. In accident cases you may have an allegation in the complaint that the defendant violated safety standards, and you look to OSHA to see whether the safety standard is there or not. It doesn't change the underlying case which here is the deceptive trade practices. You still have that.

In fact, that's what the J&J court said. You are not governed by this. You have to go back as the fact finder and let the fact finder determine whether in the J&J case there was improper conduct, the same thing you would do here. It's not contingent on the FDA determination.

MR. AGNESHWAR: That is inaccurate, your Honor. If we look at just the last sentence or the last page of the J&J case, this is the way the Supreme Court of West Virginia --

THE COURT: Just give me one moment because I have put things in different places and I would like to get it out before you read it.

(Pause.)

I have it.

MR. AGNESHWAR: This is under "Conclusion." It's the last page.

"Whether Janssen's statements and omissions in the Risperdal DACP letter and the Duragesic file card are actually false and misleading under the FDCA, the Food, Drug and Cosmetic Act, and thus constitute unfair or deceptive acts or practices under the Consumer Protection Act is a question of fact to be decided by a finder of fact."

That is their holding. The question that the finder of fact must answer in the first instance is not whether it violated some state law; it's whether the actions violated the Food, Drug and Cosmetic Act, which is a federal statute.

THE COURT: The argument there being made was because I guess there were some findings made by the FDCA that the plaintiff wanted to rely upon and would hope was dispositive, because they felt they were false and misleading findings, and was encouraging the court to find that was enough for such a finding.

MR. AGNESHWAR: And they were successful. And, in fact, the way the decision is written by the West Virginia Supreme Court is -- and the whole decision is all about what the particular provisions of the FDCA are and how they regulate advertising for prescription drugs.

THE COURT: But they didn't win the argument because what the court held was that -- they agreed that what was happening is the state wanted to argue, Please find it as a matter of law, and we're done with our case. And the court said: No, we are not going to find it as a matter of law.

They said that the findings of the FDA, or, their belief, it says, that they violated the FDCA is not sufficient to establish as a matter of law that the appellant's communications to healthcare providers were actually false and misleading in violation of the Consumer Protection Act, and that's why they say whether Janssen's statements and omissions -- the sentence you just read in the Risperdal letter and the file card are actually false and misleading under the FDCA and thus unfair is a question of fact to be decided by a finder of fact, and thus the state must present evidence that Janssen's specific statement and omissions do in fact violate the relevant laws.

MR. AGNESHWAR: I totally get that, your Honor. But the relevant law is the FDCA.

THE COURT: No, I don't think that's just the relevant law. It's clearly whether it would fall under the prescription of the Consumer Protection Act. You have to make a factual finding as to, one, whether they're misleading under the FDCA, and, then, further, would it then be a violation of the Act.

MR. AGNESHWAR: No, I don't believe that's right, your Honor. The issue the state of West Virginia lost is the collateral estoppel argument. They were arguing that because there were warning letters that the FDA issued to Janssen that disposed of the issue as a matter of law, because that was final agency action, and what the West Virginia Supreme Court said -- and this is important.

It looked only at federal law. It looked at FDA's handbooks. It looked at FDA's regulations. It looked at federal case law interpreting what warning letters are. And they concluded that a warning letter by the FDA is not a final agency action such that it would give collateral estoppel.

Therefore, the jury or the finder of fact still has to determine for itself whether the FDCA was violated. And once the FDCA is violated -- this is

how I read the sentence -- as a matter of course, the West Virginia Consumer Protection Act is violated because the FDCA provides the sum and substance of what is and is not false advertising in the prescription drug arena.

THE COURT: Let me ask the question, and I don't know that I need to get to this at the moment.

Certainly that's what that case was about, which was, the state wanted to play the role up, great, our case is going to be over. Please buy my argument that's enough to show that we have proven our case. The Court disagreed.

The question is: Is it simply -- and I don't know what Mr. Frankovitch is going to say about this. Looking at all of the practices and the marketing practices that went on that they are going to claim that BMS/Sanofi were involved in marketing Plavix, do you, one, agree that in the first instance what you have to show is that those marketing efforts would have been considered false and misleading under the FDCA?

Do you agree or disagree?

MR. FRANKOVITCH: No, I disagree with that, your Honor. I think clearly the court -- and that was the Merrell Dow case -- said the FDCA doesn't create a

cause of action for anybody. You have to establish it under whatever law you are going under. And in this instance, under the State of West Virginia Consumer Protection Act. Footnote 5 of that case clearly sets out that the Consumer Protection Act looks to the federal decisions on issues, but it's complimentary to the independent determination by the state, or, state court.

MR. AGNESHWAR: First of all, your Honor, in their brief -- and I'm reading from page 20 of their brief.

THE COURT: Which brief?

MR. AGNESHWAR: The state's brief that we cited as supplemental authority in the J&J case.

Here is what they say:

"As discussed above, state law cannot impose different standards either higher or lower than are provided by federal law on drug advertising."

Now, they may have been strategically motivated in that case because they wanted the collateral estoppel effect of warning letters, but that is the argument the West Virginia Supreme Court adopted.

I think we need to look at Merrell Dow because I think the real question here is on the slope between

Merrell Dow and Grable; where does this case fall? And I have to just quote this because, as I was preparing for argument, I read the Supreme Court's most recent decision in this area, the Gunn case. It's not so relevant here, but Chief Justice Roberts wrote:

"In outlining the contours of this slim category of federal jurisdiction, we do not paint on a blank canvas. Unfortunately, the canvas looks like one that Jackson Pollack got to first."

So the law has not been a total model of clarity. But I think if you look at Merrell Dow and Grable, and some of the other cases that have come down recently, there are some clear guidelines that are now finally developing as to when you find federal subject matter jurisdiction.

And I think, as I look at it, there are really kind of three issues:

1. Is the federal law really sort of dispositive of the issue, of some issue in the case?

No. 2. Are there institutional issues here that impact the federal agency and the regulatory scheme that go beyond the facts and the particular private dispute that's going on in the case?

And 3. What are the practical consequences of

saying that there is federal jurisdiction in a particular situation?

And Merrell Dow and Grable I think are great examples because what you had in Merrell Dow, it was your standard failure-to-warn argument, and the argument was that this label was inadequate for a host of reasons; and one of those reasons was a negligence per se count, which is that under federal law, this label was misbranded because the FDA had found it inadequate, and, therefore, that's one of the reasons why there was state law negligence. But that was not at all dispositive to the claim.

As your Honor knows well, negligence per say, what it really operates as is an evidentiary presumption. So, yes, you can bring that standard in as evidence that the defendant was negligent as evidence that the warning was inadequate, but it doesn't control the issue.

THE COURT: But isn't a labelling case even more convincing than a marketing case?

MR. AGNESHWAR: No, your Honor, because under Wyeth v. Levine, state juries are entitled to decide whether under state law a label is adequate or not. It's not really tied to the FDA regulations. But the courts recognized that the reality of a prescription

drug case is the FDA is an 800-pound gorilla. What it says and doesn't say is going to come into evidence. But if a defendant rebuts the negligence per se presumption, then all bets are off. It's off to the races. What the FDA has said it doesn't really matter anymore. So it wasn't dispositive of the issue in Merrell Dow.

Now, contrast that with Grable, where in Grable, which was an acquired title action, the sole issue in the case was whether the IRS needed to give personal service in order to foreclose on a claim. And so that issue, how that question of federal law was answered, really ended up deciding the case.

And I think this is the big difference between Merrell Dow and Grable. What the trier of fact would do in Grable was it would look at federal law and look at what federal law meant; and depending on how federal law came out, that is how the state law action came out, exactly parallel, co-extensive with. That is how the lawsuit came out.

So, now, look at our case, and we look at it in the context of Johnson & Johnson, and what the state asked the Supreme Court to do, which they did. The issue here is that there are detailed marketing schemes that the FDA has set out. The FDA has lots of

guidelines and warning letters and regulations as to what is and is not a false marketing claim.

The superiority argument is a case in point because superiority -- like the argument that Plavix is superior to aspirin, and we shouldn't have been paying that -- superiority has a very technical meaning under FDA regulations.

So if a jury was asked, say, just colloquially to answer the question: Did they accurately say that Plavix was superior to aspirin? That would be an incorrect instruction under West Virginia Consumer Protection Act standards because the real question is: What does the FDA mean by "superiority?" And that's a very different technical argument. But that is the argument that has to be made and that is what the trier of fact has to do in West Virginia.

So that puts this case on all fours with Grable in answering the question. There is no rebuttable presumption. It's not just evidence. There is no case but for the violation of FDA regulations.

What the jury or the judge will be doing in this case is it will be opening up the federal regulations looking at FDA guidance, looking at how FDA has defined "superiority," and answering the

question as to whether the fraud alleged in this case is a violation of federal law.

That makes this case 180 degrees opposite of Merrell Dow and the progeny of cases that came after including Judge Debevoise's decision in the Novartis case. Just like Merrell Dow, that case was a failure-to-warn case claim; and the 800-pound gorilla, the FDA, and what it did or didn't do came into evidence because the plaintiff obviously wanted to say: See, the FDA has done this; the FDA has done that. That's relevant to my failure-to-warn claim. But it doesn't dispose of the issue. It was still a state law claim that survived even if you found that FDA regulations were not violated.

That is not the case here under Johnson & Johnson, as that sentence I read from the last paragraph shows. You have to find a violation of the FDCA in order to prevail on your case.

THE COURT: All right. I have your argument. You disagree.

MR. FRANKOVITCH: I totally disagree, your Honor. To do what's been suggested by the defense, every case would end up being subject to removal, and you can't use the defense of the federal statute as grounds for removal. It's not part of the removal

process.

THE COURT: I understand.

Let me just ask you the question:

Do you disagree with the argument Mr. Agneshwar just made that the Court will have to find that to proceed to whether there was a violation of the West Virginia Act, you would have to first find there was a violation of the FDA?

MR. FRANKOVITCH: No, absolutely not.

THE COURT: Why not?

MR. FRANKOVITCH: Because there can be other instances that are set out, other marketing practices that aren't dictated by the --

THE COURT: Example, in your complaint.

MR. FRANKOVITCH: They put people out on the sales calls that promoted the product improperly.

THE COURT: In which way do you get back to promoting improperly because they were promoting in violation of what the FDA would permit them to say, or something else?

MR. FRANKOVITCH: West Virginia law -- as the Supreme Court noted in the Johnson & Johnson case, it's complimentary. The federal statute is complimentary to the West Virginia statute.

THE COURT: That's not the question I asked.

I said: To be able to make this claim under the West Virginia Consumer Act to show that the marketing practices were improper, will you be relying on showing that the marketing practices were in violation of FDA approvals?

MR. FRANKOVITCH: They may.

THE COURT: Will you show anything beyond that?

MR. FRANKOVITCH: I would hope so.

THE COURT: What is it? What have you pled?

MR. FRANKOVITCH: I think that we would have testimony that sales representatives called on them and made representations as to the efficacy of the drug and the pricing was appropriate because of the efficacy, and this is really a pricing issue. All of that marketing aspect would come in and compliment the potential violations of the FDCA, or, FDA.

THE COURT: But you are going to be relying on essentially arguing efficacy claims that you say are contrary to what was shown to the FDA.

MR. FRANKOVITCH: Well, we would have to prove that they had false and misleading statements, and that they knew that when they went out and marketed the drug that it was not efficacious and it was inappropriate in many cases for prescription.

THE COURT: And you would be arguing that they said things different than what they presented to the FDA and that the FDA approved.

MR. FRANKOVITCH: I don't know that the FDA approved.

THE COURT: Not approved. Marketing. But the claims.

MR. FRANKOVITCH: I'm not sure I --

THE COURT: What the effect of the drug is or how efficacious it is.

MR. FRANKOVITCH: Yes. We would establish that they did not provide adequate information and didn't provide the full picture and efficacy that they knew existed.

THE COURT: Anything else, Mr. Agneshwar?

MR. AGNESHWAR: Yes.

I think if you just look at the way -- just the last thing on this particular aspect of it -- if you just look at the way the J&J case analyzed what they have to prove, they have to prove violations of the FDCA; and if they don't, they don't have a claim.

If you just look at superiority, the question will be: What does that mean under the handbook of jury instructions in West Virginia? The question will be: What does that mean under the FDCA? That's the

sum and substance of their claim.

In terms of his argument that every case would become a federal case, that is simply not true. No. 1, this whole following the FDCA and that the violation of the FDCA, in fact, becomes then a violation of the Consumer Protection Act, that is an aspect that's unique to West Virginia. There may be other states.

But if you contrast that, they cited a Louisiana case that I argued and lost, that I made a federal question argument there. And what the court said is, no, look, when you look at the Consumer Protection statute in Louisiana, they can just show that stuff is false and misleading generally just as a matter of Louisiana common law. So violations of the FDA regulations are not essential.

THE COURT: What is unique about the West Virginia law? Let's take a look at that, please.

MR. AGNESHWAR: What's unique about it -- well, there are two aspects that are unique about it and I think that are very relevant to the sort of second and third questions, which is whether there is an institutional issue here, and the third question is whether the floodgates are going to open up and every case becomes a federal case.

The two overriding unique issues about West Virginia are:

No. 1, as the Johnson & Johnson case said, in order to determine in a prescription drug case whether something is false and misleading under state law, you look at the FDCA; and that is the beginning, the middle, and the end of the inquiry.

The issue No. 2, which makes West Virginia unique is, because of White, there is no private cause of action. There is not a compensatory damages scheme. You are not talking about a situation where a violation of FDA regs just becomes part of a compensatory damages scheme. It is only an enforcement state now, if it is that. But I argued before even that aspect is gone. But assuming it is, this is the state of West Virginia enforcing the Food, Drug and Cosmetic Act.

That is what's happening here when you take out private causes of action: one, you have to find a violation of the FDCA; two, the state can only be permitted to do enforcement, which is to get civil monetary penalties. That is why there has to be federal jurisdiction here, because that raises huge institutional issues.

THE COURT: Let me ask you this:

The statute doesn't say that they are bound by the FDCA. The way the statute is written, it says:

"Courts are to be guided by the interpretation given by the federal courts to the various federal statutes dealing with the same or similar matters."

And, therefore, then, the Court looked for guidance to the FDCA. It says "for guidance." It doesn't say, "you're bound by."

MR. AGNESHWAR: Here is the way I read it.

THE COURT: Does that make a difference?

MR. AGNESHWAR: I think it potentially makes a difference. But then you have to look at how the case law has evolved and how the West Virginia Supreme Court interpreted that. It could have gone in a very different way.

The way the West Virginia statute could have developed is that, yes, federal law is looked at as just a guideline. But at the end of the day, the standards are what is false and misleading under West Virginia law. And if it had gone that way, and the FDCA was not the beginning, middle, and end, my argument would be a lot weaker. But after J&J, that is not the way West Virginia law has developed.

The way West Virginia law has developed in the prescription drug area is that you look only at the

FDCA to determine whether the promotional and advertising practices of the pharmaceutical company were unlawful under West Virginia law. You look only at the FDCA. If you don't show that, there is no wiggle room. You don't have a cause of action.

THE COURT: You think it says that?

MR. AGNESHWAR: I think it couldn't be clearer, whether Janssen's statements and omissions are actually false and misleading under the FDCA and thus constitute unfair trade practices under the Consumer Protection Act.

THE COURT: Was it written that way? Because that's the manner in which it was being argued to them. If you look at the entire opinion, it's making clear that it could not do that because otherwise we would have a preemption argument, and it notes that by citing to the Bayer case earlier on and why they are complimentary causes of action.

I know what your arguments are. I've got them. I'm reserving on this question today. I'm not ruling on this.

MR. SALIM: Your Honor, may I add something?

THE COURT: Go ahead.

MR. SALIM: Your Honor, we literally argued this issue with the defendants in California and

Louisiana and with other defendants in Arkansas, New Mexico, all across this country, with the same statutes at issue, and with numerous federal judges, and the rulings have all been consistent, that that's just one way that you look at the issue, and state law still applies, and it's been almost uniform across the board in this country.

THE COURT: I have your cases that have gone the other way, and I think that's right, because I think when you look at the entire case law, it says that in the conclusion, I understand why you are reading it that way. I think it's doing so because in the manner in which it was argued to them and the fact that at that point it looked as if they were relying on those FDCA findings for their conclusion.

But if you look at the entire case, I think it makes very clear that it cannot be that it is the same as a finding under the FDCA because otherwise there would be a preemption argument because what you are doing is trying to preempt that federal law by making your own determination.

MR. AGNESHWAR: I respectfully disagree, your Honor.

THE COURT: You say you would disagree?

MR. AGNESHWAR: I completely disagree. If you

look at the device context where there is expressed preemption that is being upheld by the Supreme Court in Regal, you can still have state law that parallels the FDA law.

THE COURT: I understand. But I'm just telling you, I think if you look at this entire case, I think you cannot take that conclusion out of context.

I don't want to debate you anymore, Mr. Agneshwar. I'm going to decide this.

MR. AGNESHWAR: I understand.

There is one last point, not on this issue but his argument; that the floodgates will open up, I don't think is the case here because --

THE COURT: Because other courts have decided the other way.

MR. AGNESHWAR: Well, other courts have decided other statutes the other way, but this is an enforcement scheme. West Virginia does not every day bring these kinds of enforcement actions.

THE COURT: I don't know. They seem to bring an awful lot of them. I was surprised how many times West Virginia brings all these kinds of cases and how active they are in these areas.

MR. AGNESHWAR: But if you uphold federal

jurisdiction, the holding will be very narrow. It would be that in a situation where the Consumer Protection Act completely tracks the FDA, the FDCA, and the action is a claim for enforcement which parallels what the FDA --

THE COURT: It doesn't completely track it. But that's okay. Please, I have your arguments. I don't need more.

Yes, Mr. Salim.

MR. SALIM: I was just going to ask your Honor while we are all here about our next regular scheduling conference. We would request that the Court not set it until October because we are trying to resolve a lot of issues, and I don't know when the Court had in mind setting it.

THE COURT: I think your next one is going to be the status. It will be before Judge Bongiovanni.

You're just talking about discovery issues.

MR. SALIM: Right. Would that be in October? Did the Court set it yet?

THE COURT: Was it in the last order?

MR. SALIM: No, your Honor. You said to let you know where we were the next time we got together and then we would set it.

THE COURT: You can talk to Judge

Bongiovanni's chambers about setting that up, and you can assume that you'll get a decision on this sometime in September on the West Virginia matter.

MR. SALIM: Thank you, your Honor.

THE COURT: Thank you for all your arguments and your briefing.

THE CLERK: All rise.

(Proceedings concluded.)

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C E R T I F I C A T E

I, **Vincent Russoniello**, Official United States Court Reporter and Certified Court Reporter of the State of New Jersey, do hereby certify that the foregoing is a true and accurate transcript of the proceedings as taken stenographically by and before me at the time, place and on the date hereinbefore set forth.

I do further certify that I am neither a relative, nor employee, nor attorney, nor counsel of any of the parties to this action, and that I am neither a relative nor employee of such attorney or counsel and that I am not financially interested in this action.

S/Vincent Russoniello
Vincent Russoniello, CCR
Certificate No. 675
Date: August 27, 2013

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